

**SCOTT ROSEFF, M.D., FACOG, P.A.**

Board Certified, Reproductive Endocrinology & Infertility  
Diplomate, American Board of Obstetrics and Gynecology

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**W.E. C.A.R.E.**

West Essex Center for Advanced Reproductive Endocrinology

Dockets Management Branch (HFA-305)

Food and Drug Administration

5360 Fishers Lane, room 1061

Rockville, MD 20852

December 20, 1999

Re: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To Whom It May Concern:

As a practicing physician Board Certified in Reproductive Endocrinology/Infertility, I adamantly oppose a particular segment of the above-referenced proposal.

The rule necessitating testing of egg donors prior to an IVF cycle, freezing resultant embryos, and quarantining them until 6 months later when the egg donor is retested for infectious diseases is unacceptable. The ASRM stated, "There is no evidence that oocytes, embryos, or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal." "Quarantining embryos will significantly increase costs". Transfer of frozen (quarantined) embryos will lower the IVF pregnancy rate, as fresh embryos typically implant with a higher frequency compared to frozen embryos. An "estimated 9,000 embryos will die each year" unnecessarily due to the proposed freezing mandate. Finally, as most egg donors are young, mobile women, many batches of embryos may be "unusable" because egg donors may not be available 6 months later to be retested.

Thank you for taking the time to read and understand my concerns, all of which have been voiced by my colleagues as well. I anticipate your reconsideration of this unfair and impractical regulation, the implications of which would be devastating to the practice of Reproductive Medicine and the delivery of proper healthcare to women in the United States.

Sincerely,

Scott J. Roseff, MD, FACOG

Co-Director, W.E. C.A.R.E.

Clinical Assistant Professor, Dept. Ob/Gyn

UMDNJ - New Jersey School of Medicine

cc: Michael Darder, MD - IVF New Jersey

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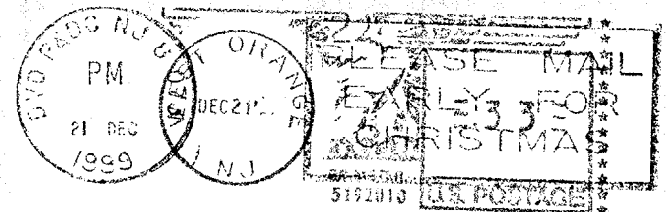
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